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EXAMINER

HINES, JANA A

ART UNIT PAPER NUMBER

1645

DATE MAILED: 09/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/763,415

Applicant(s)

FISH, FALK

Examiner

Ja-Na Hines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-10 and 12-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,4 and 5 is/are allowed.
- 6) ☒ Claim(s) 6-10 and 12-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Amendment Entry

1. The amendment filed June 29, 2004 has been entered. Claims 1,4-8 and 10 have been amended. Claims 2-3 and 11 have been cancelled. Claims 13-14 have been newly added. Claims 1, 4-10 and 12-14 are under consideration in the office action.

Withdrawal of Rejections

2. The following rejections have been withdrawn in view of applicants' amendments and arguments:

- a) The rejection of claims 1-2 and 4-5 under 35 U.S.C. 112, first paragraph; and
- b) The rejection of claims 7-8 and 10 under 35 U.S.C. 112, second paragraph.

Response to Arguments

3. Applicant's arguments filed June 29, 2004 have been fully considered but they are not persuasive.

4. The rejection of claims 10 and 14 under 35 U.S.C. 102(b) as being anticipated by Paisey et al., is maintained for the reasons already of record. The claims are drawn to a kit which comprises a hair removal means; a diluent; a means for measuring the level of blood component and glucose; and a means for calculation. The dependant claim is drawn to measuring hemoglobin.

Applicants argue that the art no longer applies because claim 6 has been amended to recite a different means for measuring the level of hemoglobin. In response to applicant's argument that the references fail to show certain features of applicant's

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invention, it is noted that the features upon which applicant relies i.e., measuring the level of glucose in the sample selected from the group consisting of fluorescence, chemiluminescence, bioluminescence, colorimetric method and electrochemical methods are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Therefore applicants' argument is not persuasive.

It is noted that the components in a kit are commercially available which eliminates the variability that can occur when performing the assay. Although the reference does not specifically disclose a kit, it is inherently obvious to any one of ordinary skill in the art to create a kit comprising the recited components to determine the level of glucose in a sample and achieve economic efficiency.

Therefore, Paisey et al., teach components which meets the limitations of the claims by teaching a kit which comprises a hair removal means; a diluent; a means for measuring the level of blood component and glucose; and a calculation just as claimed and the rejection is maintained.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

regards as the invention. Claim 9 recites the limitation "said signals" in the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 6-8 and 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paisley et al., in view of Sigma Chemical Company Catalog 1992.

The claims are drawn to a kit which comprises a means for obtaining a hair sample; a means for measuring the level of blood components; separation means; and a means for measuring the level of blood component and glucose; and a means for calculation. The dependant claims are drawn to separation means and suitable diluents.

Paisley et al., teach glycosylation of hair and the measure of chronic hyperglycaemia. The authors took hair samples from patients wherein the hair was taken from behind the ear and cut into 100mg samples (page 670). Therefore Paisley et al., teach a means for obtaining hair or urine samples. The patients also had blood taken for measurement of glycosylated haemoglobin (page 670). The hair samples were incubated with thiobarbituric acid solution, distilled water, azide solutions, and guanidinium hydrochloride (page 670). Also serial dilutions of hexoses, glucose, galactose, sialic acid, mannose and arabinose were performed (page 670). Thereby teaching suitable diluents in which the blood obtained from the hair samples was diluted. Paisley et al.,

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teach the use of metabolic inhibitors such as thichloroacetic acid (page 670). Also the authors inherently teach separation of red blood cells from the blood sample in order to determine the glycosylated hemoglobin concentration (page 669). A means for measuring the level of a blood component such as haemoglobin in the sample was achieved by agar gel electrophoresis (page 670). Gas-liquid chromatography analyzed sugar in the samples (page 670). Centrifugation techniques are also taught (page 670). The authors also note that glucose may be bound to the mature hair shaft from sweat and other extraneous substances (page 671). A means for calculating the level of glucose in the blood of the sample was based on the statistical results achieved by evaluating the statistical differences and regression analysis (page 670). Table 1 glycosylation of samples of scalp hair from normal and diabetic subjects. However Paisey et al., do not teach the use of equivalent and well-known glucose measurement techniques or the use of well known functionally equivalent reagents.

Paisey et al., teach a separation step that lyses the red blood cells in order to release the analyte to be tested. Applicants have instead used an alternative and functionally equivalent red cell lysing reagent to accomplish the same step. This red cell lysis reagent was commercially available from Sigma and well known in the art of the determining the analysis of blood cell components. Thus the methods are functionally equivalent. Similarly, Paisey et al., teach the measurement of glucose using a different measuring technique than what is now recited. However, the prior art teach that measurement of glucose could have been done using an enzymatic colorimetric diagnostic instead. No more than routine skill would have been required to use this

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commercially available and well known diagnostic which determines the level of glucose in place of the technique Paisey et al., used to determine the level of glucose.

It is noted that the components in a kit are commercially available which eliminates the variability that can occur when performing the assay. Although the reference does not specifically disclose a kit, it is obvious to any one of ordinary skill in the art to create a kit comprising the recited components to determine the level of glucose in a sample and achieve economic efficiency.

Thus, it would have been prima facie obvious at the time of applicants invention to modify the kit that includes of a means for obtaining a hair sample; a means for measuring the level of blood components; a separation means; a means for measuring the level of blood component and glucose; and a means for calculation wherein the modification comprises using an alternative and functionally equivalent measuring means and a lysis reagent. In this case, one would have a reasonable expectation of success by incorporating the lysis reagent and colorimetric determination method since it was already known in the art to lyse blood cells in order to release their contents and allow the accessible contents such as glucose to be colorimetrically measured. Moreover, no more than routine skill would have been required to use an alternative yet functionally equivalent reagents and techniques, since only the expected results would have been obtained; thus the use of alternative and functionally equivalent reagents and colorimetric methods would have been desirable to those of ordinary skill in the art based on the known ability to lyse cells and measure glucose.

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7. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Paisey et al., in view of Albarella et al., (US Patent 4,017,261). Paisey et al., have been discussed above however, Paisey et al., does not teach using a test strip to measure glucose and hemoglobin and glucose.

The claims are drawn to a kit which comprises a means for obtaining a hair sample; a means for measuring the level of blood components; separation means; and a means for measuring the level of blood component and glucose; a means for calculation and a test strip and instrument that detects and analyses such. The dependant claims are drawn to separation means and suitable diluents.

Paisey et al., teach glycosylation of hair and the measure of chronic hyperglycaemia. The authors took hair samples from patients wherein the hair was taken from behind the ear and cut into 100mg samples (page 670). Therefore Paisey et al., teach a means for obtaining hair or urine samples. The patients also had blood taken for measurement of glycosylated haemoglobin (page 670). The hair samples were incubated with thiobarbituric acid solution, distilled water, azide solutions, and guanidinium hydrochloride (page 670). Also serial dilutions of hexoses, glucose, galactose, sialic acid, mannose and arabinose were performed (page 670). Thereby teaching suitable diluents in which the blood obtained from the hair samples were diluted. Also the authors inherently teach separation of red blood cells from the blood sample in order to determine the glycosylated hemoglobin concentration (page 669). A means for measuring the level of a blood component such as haemoglobin in the sample was achieved by agar gel electrophoresis (page 670). Gas-liquid chromatography analyzed sugar in the samples (page 670). Centrifugation techniques are also taught (page 670). The authors also note

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that glucose may be bound to the mature hair shaft from sweat and other extraneous substances (page 671). A means for calculating the level of glucose in the blood of the sample was based on the statistical results achieved by evaluating the statistical differences and regression analysis (page 670). Table 1 glycosylation of samples of scalp hair from normal and diabetic subjects. However Paisey et al., do not teach the testing and analysis of the hemoglobin and glucose using a test strip.

Albarella et al., (US Patent 4,017,261) teach a test device for determining the presence or concentration of a component in a test sample (col. 8 lines 60-63). The test strip can provide qualitative or quantitative measurements of hemoglobin, peroxide and glucose (col. 11 lines 15-30). The device includes a test pad comprising a suitable carrier matrix incorporating an indicator reagent composition capable of interacting with the test sample component to produce a detectable response (col. 8 lines 63-66). The response can be a visually detectable response or a response that is detectable by an instrument (col. 8-9 lines 66-2). The test sample can be analyzed using a spectrophotometer or colorimeter to precisely determine the degree of color transition (col. 28 lines 25-30).

It is noted that the components in a kit are commercially available. The reference specifically disclose a device for use in a kit, thus it is obvious to any one of ordinary skill in the art to create a kit comprising the recited components to determine the level of glucose in a sample and achieve economic efficiency.

Thus, it would have been prima facie obvious at the time of applicants invention to modify a kit which includes a means for obtaining a hair sample; a means for measuring the level of blood components; a separation means; a means for measuring the level of blood component and glucose; and a means for calculation wherein the

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modification comprises using an alternative and functionally equivalent measuring means such as a test strip to measure hemoglobin and glucose. In this case, one would have a reasonable expectation of success by incorporating the test strip since it was already known in the art to colorimetrically measure hemoglobin and glucose. Moreover, no more than routine skill would have been required to use an alternative yet functionally equivalent reagents and techniques, since only the expected results would have been obtained; thus the use of alternative and functionally equivalent reagents and colorimetric methods would have been desirable to those of ordinary skill in the art based on the known ability of measure glucose and hemoglobin.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines *JNH*
September 13, 2004

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